

S. Abbas Shobeiri, M.D.

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IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

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IN RE: ETHICON, INC., PELVIC	Master File No.
REPAIR SYSTEM PRODUCTS	2:12-MD-02327
LIABILITY LITIGATION	MDL 2327

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THIS DOCUMENT RELATES TO THE JOSEPH R. GOODWIN
FOLLOWING CASES IN WAVE 1 OF U.S. DISTRICT JUDGE
MDL 200:

Dorothy Baugher v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01053

Denise Sacchetti v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01148

Sheri Scholl, et al. v. Ethicon, Inc.
Civil Action No. 2:12-cv-00738

Lisa Thompson, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01199

Roberta Warmack, et al. v. Ethicon, Inc., et al
Civil Action No. 2:12-cv-1150

Rebecca Wheeler, et al. v Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01088

Thelma Wright v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01090

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VIDEOTAPED DEPOSITION OF

S. ABBAS SHOBEIRI, M.D.

Fairfax, Virginia

February 27, 2016

Reported by: Denise D. Vickery, CRR/RMR

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<p>1 Devising retractors to help during</p> <p>2 sacrocolpopexies, you know.</p> <p>3 Q. Okay. But those have not been used?</p> <p>4 A. Quite honestly, those are the things</p> <p>5 I devised and by the time that I decided it would</p> <p>6 be a good time to patent them, they -- somebody</p> <p>7 else beat them to the market.</p> <p>8 Q. Have you ever designed a</p> <p>9 mid-urethral sling?</p> <p>10 A. Have I ever designed a mid-urethral</p> <p>11 sling? Well, we -- we create -- I created</p> <p>12 ultrasound Phantoms, and we did cut like sling</p> <p>13 tapes that we implanted into the Phantoms.</p> <p>14 Q. Okay. Well, I'm going to get into</p> <p>15 your ultrasound opinions here in a minute, but</p> <p>16 right now I'm asking: Did you ever design for</p> <p>17 use in a patient a mid-urethral sling?</p> <p>18 A. Well, are you talking about a</p> <p>19 synthetic sling?</p> <p>20 Q. Sure.</p> <p>21 A. No, I have not designed a synthetic</p> <p>22 sling that has gone to the market.</p> <p>23 Q. Okay. And have you ever designed a</p> <p>24 device which has been implanted into a patient</p>	<p>1 Q. Well, obviously I don't want you to</p> <p>2 violate a confidentiality agreement.</p> <p>3 A. Uh-huh.</p> <p>4 Q. But you're going to have to give me</p> <p>5 some idea for whom, when, what in general was</p> <p>6 involved.</p> <p>7 A. Hmm. AMS.</p> <p>8 Q. Okay. Tell me about what you did</p> <p>9 for AMS in general.</p> <p>10 MS. THOMPSON: Only to the extent</p> <p>11 that you can under your agreement.</p> <p>12 THE WITNESS: Well, we trialed</p> <p>13 the -- we trialed TOPAS.</p> <p>14 BY MR. OTTAWAY:</p> <p>15 Q. Trialed? I'm sorry. Trialed TOPAS?</p> <p>16 A. Uh-huh. T-O-P-A -- is it S or Z? I</p> <p>17 don't know. I think that's it.</p> <p>18 Q. Okay. And what is TOPAS?</p> <p>19 A. It's a fecal incontinence product.</p> <p>20 Q. And does it involve any kind of</p> <p>21 synthetic mesh?</p> <p>22 A. Yes.</p> <p>23 Q. Okay. What kind of mesh product is</p> <p>24 used in TOPAS that you were involved with?</p>
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<p>1 that has been approved or vetted by the FDA?</p> <p>2 A. No.</p> <p>3 Q. Are you an expert in FDA regulatory</p> <p>4 matters?</p> <p>5 A. I know a lot about FDA regulatory</p> <p>6 matters.</p> <p>7 Q. My question was: Do you consider</p> <p>8 yourself an expert in FDA regulatory issues?</p> <p>9 A. Could you define "expert"?</p> <p>10 Q. You -- you're the one that mentioned</p> <p>11 it. I'm just asking you if you consider yourself</p> <p>12 to be an expert in FDA regulatory matters.</p> <p>13 A. I know more than a lot of other</p> <p>14 people.</p> <p>15 Q. Okay. Have you worked -- been hired</p> <p>16 by the FDA to work on regulatory issues?</p> <p>17 A. No.</p> <p>18 Q. Have you ever worked with a device</p> <p>19 manufacturer to gain FDA approval for a medical</p> <p>20 device?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. Tell me about that.</p> <p>23 A. I'm not sure if I can because we</p> <p>24 signed confidentiality agreement.</p>	<p>1 A. Well, we -- it was their -- their</p> <p>2 version of polypropylene.</p> <p>3 Q. And how is it -- how does it differ</p> <p>4 from a polypropylene used in TVT-O if you know?</p> <p>5 A. It's just the way it's woven is</p> <p>6 probably different.</p> <p>7 Q. Okay. And tell me how the way it is</p> <p>8 woven is different than TVT.</p> <p>9 A. So, for example, TVT-O when you</p> <p>10 implant it and it frays and the little pieces of</p> <p>11 mesh come undone, you can actually see it on your</p> <p>12 hand. That is, when you pull the sheet out, the</p> <p>13 sling rolls into sort of tubular structure and,</p> <p>14 you know, just as it gets stretched, the -- the</p> <p>15 holes in the mesh are not as the size that they</p> <p>16 were designed. So -- so it's just different.</p> <p>17 Q. Okay. And, again, how is it</p> <p>18 different? I'm -- I'm -- is it --</p> <p>19 A. So the TVT-O when you insert it,</p> <p>20 when you take the plastic sheet out, you know, it</p> <p>21 frays. The little piece of mesh can come on your</p> <p>22 hand and then it can also roll, and also it</p> <p>23 stretches where the holes that are there sort of</p> <p>24 become smaller.</p>

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<p>1 Q. Right. You told me that, but I want</p> <p>2 to know how the polypropylene used in TOPAS</p> <p>3 differs from the polypropylene used in TVT-O.</p> <p>4 A. It's just different design.</p> <p>5 Q. Okay. And how is the design</p> <p>6 different?</p> <p>7 A. The -- the weave is different.</p> <p>8 Q. Okay. Weave.</p> <p>9 A. Uh-huh.</p> <p>10 Q. Anything else?</p> <p>11 A. I think that's mostly what</p> <p>12 differentiates them, and also the -- just the way</p> <p>13 it designed. It's not -- doesn't stretch like</p> <p>14 TVT-O.</p> <p>15 Q. Okay. So its application is</p> <p>16 different?</p> <p>17 A. No. It's just woven differently, so</p> <p>18 it wouldn't be as stretchy.</p> <p>19 Q. Does it differ -- differ in chemical</p> <p>20 property?</p> <p>21 MS. THOMPSON: Object to form.</p> <p>22 THE WITNESS: The chemical</p> <p>23 property. The polypropylene? When you say</p> <p>24 "chemical property," like is it like made</p>	<p>1 page 35 lines 16-19.)</p> <p>2 THE WITNESS: I haven't looked at</p> <p>3 their final material but, I mean, we did</p> <p>4 their anatomical studies.</p> <p>5 BY MR. OTTAWAY:</p> <p>6 Q. Okay. So is the answer to my</p> <p>7 question you have or have not prepared written</p> <p>8 materials that will go with the product if it is</p> <p>9 released to the market?</p> <p>10 A. I gave them reports. So what they</p> <p>11 are using, it is their prerogative.</p> <p>12 Q. Okay. Well, for example, have you</p> <p>13 ever prepared a warning or IFU that would</p> <p>14 accompany a device --</p> <p>15 A. No.</p> <p>16 Q. -- on the market? No?</p> <p>17 A. No.</p> <p>18 Q. Okay. Did you do that for or were</p> <p>19 you asked to do that by AMS for TOPAS?</p> <p>20 MS. THOMPSON: Object to form.</p> <p>21 THE WITNESS: No.</p> <p>22 Thanks.</p> <p>23 BY MR. OTTAWAY:</p> <p>24 Q. Have you ever written a warning for</p>
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<p>1 differently or --</p> <p>2 BY MR. OTTAWAY:</p> <p>3 Q. Yes.</p> <p>4 A. -- what do you mean?</p> <p>5 So, no, it's polypropylene and it's</p> <p>6 just woven differently.</p> <p>7 Q. All right. Is TOPAS on the market?</p> <p>8 A. It -- well, it has gone through its</p> <p>9 FDA trial, and I believe it just got a hearing</p> <p>10 recently.</p> <p>11 Q. Okay. What exactly was your role in</p> <p>12 the trial for TOPAS mesh?</p> <p>13 A. I studied the anatomical course of</p> <p>14 the sling, both in cadavers and in live patients,</p> <p>15 with ultrasound, and we did the trials.</p> <p>16 Q. Okay. Were you involved in</p> <p>17 preparing any written materials that were to</p> <p>18 accompany or are to accompany TOPAS if it's</p> <p>19 released to the market?</p> <p>20 A. Could you repeat that question?</p> <p>21 MR. OTTAWAY: Can you read that</p> <p>22 back to him again? I'm not sure I can ask</p> <p>23 it any better.</p> <p>24 (The reporter read the record on</p>	<p>1 any product?</p> <p>2 MS. THOMPSON: Object to form.</p> <p>3 THE WITNESS: Have I ever written</p> <p>4 a warning for any products? No.</p> <p>5 BY MR. OTTAWAY:</p> <p>6 Q. Have you ever had any special</p> <p>7 education about warnings and how they should be</p> <p>8 written?</p> <p>9 MS. THOMPSON: Object to form.</p> <p>10 THE WITNESS: Well, I have read a</p> <p>11 lot of IFUs and in medical school we, you</p> <p>12 know, we learn about these things.</p> <p>13 BY MR. OTTAWAY:</p> <p>14 Q. Well, other than your medical school</p> <p>15 training and reading IFUs, have you had any</p> <p>16 specialized training in the preparation or</p> <p>17 dissemination of warnings?</p> <p>18 A. Could you expand on that?</p> <p>19 Q. Not really.</p> <p>20 A. Uh-huh.</p> <p>21 MR. OTTAWAY: You want to ask it?</p> <p>22 Read the question again.</p> <p>23 (The reporter read the record on</p> <p>24 page 37 lines 14-17.)</p>

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<p>1 MS. THOMPSON: Object to form.</p> <p>2 THE WITNESS: So like have I gone</p> <p>3 to law school or --</p> <p>4 BY MR. OTTAWAY:</p> <p>5 Q. I know you haven't been to law</p> <p>6 school because I've read your resumé.</p> <p>7 A. Uh-huh.</p> <p>8 Q. My question stands as asked. Can</p> <p>9 you answer it?</p> <p>10 A. Besides the training I have had, I</p> <p>11 have not had any other training.</p> <p>12 Q. So confined to what you learned in</p> <p>13 medical school and in reading IFUs?</p> <p>14 MS. THOMPSON: Object to form.</p> <p>15 THE WITNESS: Yes. I'm not a</p> <p>16 lawyer.</p> <p>17 BY MR. OTTAWAY:</p> <p>18 Q. Are you a member of the -- what I'll</p> <p>19 refer to as -- AUGS? If I say "AUGS," do you</p> <p>20 know what I mean?</p> <p>21 A. Yes.</p> <p>22 Q. Okay. What -- what, for the ladies</p> <p>23 and gentlemen of the jury, is AUGS?</p> <p>24 A. The American Urogyne Society.</p>	<p>1 urinary incontinence can and does adversely</p> <p>2 affect the quality of life for women?</p> <p>3 A. I agree with you.</p> <p>4 Q. Do you agree with me that</p> <p>5 mid-urethral slings are the standard of care for</p> <p>6 the treatment of stress urinary incontinence?</p> <p>7 MS. THOMPSON: Object to form.</p> <p>8 THE WITNESS: The surgical</p> <p>9 standard of care, yeah.</p> <p>10 BY MR. OTTAWAY:</p> <p>11 Q. Okay. Is that position shared by</p> <p>12 the organizations we just mentioned of which you</p> <p>13 are a member, AUGS and ACOG?</p> <p>14 A. I think those are the standard of</p> <p>15 care, yeah.</p> <p>16 Q. And would you agree with me that</p> <p>17 TVT-O is a type of mid-urethral sling?</p> <p>18 A. That's debatable whether it ends up</p> <p>19 in mid-urethral or not.</p> <p>20 Q. Do you believe it's a mid-urethral</p> <p>21 sling or not?</p> <p>22 A. I believe it's not placed</p> <p>23 mid-urethral.</p> <p>24 Q. Okay. Have either AUGS or ACOG</p>
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<p>1 Q. How long have you been a member of</p> <p>2 that organization?</p> <p>3 A. Probably close to 20 years.</p> <p>4 Q. Have you reviewed abstracts for that</p> <p>5 organization and prepared programs for that</p> <p>6 organization?</p> <p>7 A. Yes.</p> <p>8 Q. Are you a member of the American</p> <p>9 College of Surgeons?</p> <p>10 A. Yes.</p> <p>11 Q. Gynecological surgeons.</p> <p>12 What I will refer to as ACOG?</p> <p>13 A. They're different. College of</p> <p>14 Surgeons and ACOG are different.</p> <p>15 Q. And are you a member of both?</p> <p>16 A. Yes.</p> <p>17 Q. And when you say "ACOG," can you</p> <p>18 tell the jury what you're referring to?</p> <p>19 A. American College of Obstetricians</p> <p>20 and Gynecologists.</p> <p>21 Q. How long have you been a member of</p> <p>22 ACOG?</p> <p>23 A. Probably 25 years.</p> <p>24 Q. Do you agree with me that stress</p>	<p>1 taken a position that TVT-O is not a mid-urethral</p> <p>2 sling?</p> <p>3 A. Let me correct myself.</p> <p>4 In the TVT-O IFU, where they say to</p> <p>5 make the incision does not facilitate putting the</p> <p>6 sling in mid-urethral. ACOG and AUGS support</p> <p>7 mid-urethral slings.</p> <p>8 Q. Have ACOG or AUGS taken a position,</p> <p>9 to your knowledge, indicating that TVT-O is not</p> <p>10 within the category of mid-urethral slings?</p> <p>11 A. I believe they have not delineated</p> <p>12 that.</p> <p>13 Q. All right. We've been going about</p> <p>14 45 minutes, Doctor. Let's take a break.</p> <p>15 And anytime you need to take a</p> <p>16 break, by the way, if you'll just answer the</p> <p>17 question on the table and tell me you need to</p> <p>18 take a break, we'll do it at your convenience as</p> <p>19 well.</p> <p>20 Fair enough?</p> <p>21 A. That's great.</p> <p>22 MR. OTTAWAY: Okay.</p> <p>23 THE VIDEOGRAPHER: Time now is</p> <p>24 10:49. We are going off the record.</p>

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<p>1 A. True.</p> <p>2 Q. So today are we on the \$750 an hour</p> <p>3 or the \$6,000 a day plus expenses?</p> <p>4 A. 6,000 divided by half because we'll</p> <p>5 be utilizing half a day.</p> <p>6 Q. So \$3,000 for half a day?</p> <p>7 A. Yes.</p> <p>8 Q. And did you prepare this report</p> <p>9 yourself?</p> <p>10 A. Yes.</p> <p>11 Q. Okay. It's got an Appendix B</p> <p>12 associated with it, which is a list of reliance</p> <p>13 materials.</p> <p>14 A. Hmm?</p> <p>15 Q. A list of reliance materials.</p> <p>16 A. Okay.</p> <p>17 Q. Did you assemble those yourself?</p> <p>18 A. The references? Yes.</p> <p>19 Q. Okay. Now, part of those references</p> <p>20 are what I have marked as 2.</p> <p>21 (Document marked, for</p> <p>22 identification purposes, as Defendant's</p> <p>23 Exhibit No. 2.)</p> <p>24 BY MR. OTTAWAY:</p>	<p>1 other documents produced by Ethicon in this</p> <p>2 litigation?</p> <p>3 A. Not that I recall.</p> <p>4 Q. So as I understand it, those in</p> <p>5 front of you are the ones you've reviewed and</p> <p>6 you've reviewed no others?</p> <p>7 A. Unless I quoted them in my report.</p> <p>8 Q. Okay. Those are the ones I think</p> <p>9 you mention in your report.</p> <p>10 A. Then that's what it is.</p> <p>11 Q. Okay. Now, you made no independent</p> <p>12 effort to go through other documents produced by</p> <p>13 Ethicon in this litigation?</p> <p>14 A. No.</p> <p>15 Q. Some of those documents were</p> <p>16 originally in French. I don't know whether you</p> <p>17 speak French. Do you?</p> <p>18 A. No.</p> <p>19 Q. Okay. Who provided the translations</p> <p>20 of those documents for you?</p> <p>21 A. I haven't skimmed over those.</p> <p>22 Q. Please, you're free to look at them</p> <p>23 anytime you want.</p> <p>24 A. Hmm. So this document you're</p>
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<p>1 Q. And for your benefit, Doctor, I will</p> <p>2 tell you those are documents that have been</p> <p>3 produced by Ethicon in this litigation.</p> <p>4 A. I'm just going over them.</p> <p>5 Q. Of course. Take your time.</p> <p>6 A. (Reviewing document). Yes.</p> <p>7 Q. How did you get those documents?</p> <p>8 A. It was sent to me.</p> <p>9 Q. By?</p> <p>10 A. Motley Rice.</p> <p>11 Q. Do you know how many documents have</p> <p>12 been produced in this litigation by Ethicon?</p> <p>13 A. How many what?</p> <p>14 Q. Documents have been produced by</p> <p>15 Ethicon in this litigation?</p> <p>16 A. Not really.</p> <p>17 Q. Did you go through additional</p> <p>18 documents and cull those out, or were those the</p> <p>19 documents that were provided to you?</p> <p>20 A. I went through all the documents</p> <p>21 that was provided to me. I went over this</p> <p>22 because making sure that I had seen this before.</p> <p>23 Q. Okay. And other than those</p> <p>24 documents in front of you, have you reviewed any</p>	<p>1 talking about is on which page? Are you talking</p> <p>2 about this one?</p> <p>3 Q. There are two that are translated</p> <p>4 from French into English in whole and part.</p> <p>5 A. Uh-huh.</p> <p>6 Q. I just wanted to know whether you</p> <p>7 did the translations or who did them.</p> <p>8 A. That's how they came.</p> <p>9 Q. Okay. And the literature portion of</p> <p>10 Exhibit B, did you assemble that yourself?</p> <p>11 A. The ones that I have quoted?</p> <p>12 Q. Yes.</p> <p>13 A. Yes.</p> <p>14 Q. Okay. When we talk about</p> <p>15 literature, Doctor, is there a hierarchy of</p> <p>16 literature that physicians rely upon, some more</p> <p>17 reliable than others?</p> <p>18 A. Could you refine it?</p> <p>19 Q. Yeah, that was a terrible question.</p> <p>20 You're right to ask me to repeat it.</p> <p>21 If you as a physician review</p> <p>22 literature, do you in your own mind differentiate</p> <p>23 between, say, peer-reviewed random controlled</p> <p>24 trials and individual case studies?</p>

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<p>1 Q. I think we've covered this before, 2 but I just want to make sure. 3 Exhibit 2 there. Are those the only 4 Ethicon documents upon which you rely to support 5 the opinion at page 19 of your report? 6 A. Go ahead. 7 Q. It starts out "I reviewed Ethicon 8 documents." 9 Are those the only Ethicon documents 10 you reviewed to support that part of your 11 opinion? 12 A. I believe so. 13 Q. All right. When you say "mesh 14 contraction," what do you mean? 15 A. Mesh being smaller than it was 16 implanted. 17 Q. Okay. And when does the literature 18 first discuss that as a potential with 19 polypropylene mesh? 20 A. Probably somewhere in 1950s, '60s 21 with mesh for hernia repair. 22 Q. And mesh has been used -- 23 polypropylene mesh has been used for years in 24 surgical situations, whether it's sutures or</p>	<p>1 Q. Okay. If you go to page 5 of your 2 report, Doctor. 3 A. Go ahead. 4 MR. OTTAWAY: We're going to get 5 into some of your opinions. 6 How long have we been going, 7 Ms. Reporter? 8 THE VIDEOGRAPHER: 43 minutes. 9 MR. OTTAWAY: 43. Let's go ahead 10 and take another break. I told you we'd 11 break about every 45 minutes, and this is a 12 good time to do so. 13 THE WITNESS: Okay. Has it been 14 45 minutes? 15 MR. OTTAWAY: It has. Have you 16 been having fun and time flies when you're 17 having fun? 18 THE WITNESS: Yeah, it's just -- 19 that's fine. We can take like five 20 minutes; right? 21 THE VIDEOGRAPHER: Time now is 22 11:49. We are going off the record. 23 (Recess - 11:49 a.m.. 24 - 12:03 p.m.)</p>
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<p>1 woven mesh or medical devices such as 2 mid-urethral slings? Is that a true statement? 3 A. It has been used for hernia repair 4 and has had complications, and people have tried 5 to move away from it into other type of products. 6 Q. But that's been known, this 7 contraction issue you discuss, for many years in 8 the medical community to people who practice in 9 the profession that you do? 10 MS. THOMPSON: Object to form. 11 THE WITNESS: So do people know 12 that mesh contracts? 13 BY MR. OTTAWAY: 14 Q. Yes. 15 A. I think they are told that it 16 doesn't, and it depends on how much of the 17 literature they are reading and how critically 18 they are looking at the literature. 19 Q. Okay. Someone who looks at the 20 literature would be able to find support for that 21 proposition? 22 A. That mesh contracts? 23 Q. Yes. 24 A. Yes.</p>	<p>1 THE VIDEOGRAPHER: Time now is 2 12:03. We are back on the record. This is 3 the beginning of disk No. 2. 4 BY MR. OTTAWAY: 5 Q. Dr. Shobeiri, I had referred you 6 when we broke to page 5 of your report, which is 7 titled "Summary of Opinions." 8 A. Yes, sir. 9 Q. Have you had a chance to review that 10 while we were on break? 11 A. No. I was actually looking at IFU. 12 Q. Okay. Well, I take it you're 13 familiar with these opinions? 14 A. Yes. 15 Q. And I want to ask you about them -- 16 A. Uh-huh. 17 Q. -- one at a time. 18 A. Sure. 19 Q. Tell me about opinion number 1. 20 What is your opinion and upon what do you base 21 it? 22 A. Mesh complications are unlike those 23 seen with the other pelvic surgery in terms of 24 onset, frequency, severity, character,</p>

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<p>1 Q. Anything else you need to tell me</p> <p>2 about opinion number 6?</p> <p>3 A. Well, the last sentence that it says</p> <p>4 results in significant morbidity for the patient.</p> <p>5 Once you have scarring around the nerve causing</p> <p>6 the pain, a lot of times even if when you go and</p> <p>7 remove the sling, the scarring is still there and</p> <p>8 the pain may not be reduced, depending on when</p> <p>9 the original sling was placed.</p> <p>10 Q. And do you reference specific</p> <p>11 literature to support that opinion?</p> <p>12 MS. THOMPSON: Object to form.</p> <p>13 THE WITNESS: Am I citing a</p> <p>14 specific reference for relating to that? I</p> <p>15 think it is in my references. We can look</p> <p>16 it up.</p> <p>17 BY MR. OTTAWAY:</p> <p>18 Q. We'll do that at the next break,</p> <p>19 Doctor, and you can tell me. I don't want to</p> <p>20 take your time here.</p> <p>21 But if you do reference a specific</p> <p>22 piece of literature to support number 6, I would</p> <p>23 appreciate you finding it for me on the next</p> <p>24 break, okay?</p>	<p>1 the leg pain that the patients experience.</p> <p>2 Q. So it's groin and leg pain.</p> <p>3 And do you have in your mind what an</p> <p>4 acceptable rate of pain would be?</p> <p>5 MS. THOMPSON: Object to form.</p> <p>6 BY MR. OTTAWAY:</p> <p>7 Q. You say this is "unacceptably high."</p> <p>8 Do you have an opinion about what</p> <p>9 would be acceptable, in your opinion?</p> <p>10 A. Acceptable rate --</p> <p>11 MS. THOMPSON: Object to form.</p> <p>12 THE WITNESS: -- of chronic pain</p> <p>13 for me would be none.</p> <p>14 BY MR. OTTAWAY:</p> <p>15 Q. Okay. So anything above zero is an</p> <p>16 unacceptably high rate of chronic pain to you?</p> <p>17 MS. THOMPSON: Object to form.</p> <p>18 THE WITNESS: I don't want my</p> <p>19 patients to have any chronic pain.</p> <p>20 BY MR. OTTAWAY:</p> <p>21 Q. Okay. I'm just asking what your</p> <p>22 opinion is here, Doctor.</p> <p>23 Was my statement correct?</p> <p>24 A. My opinion is that if the patient</p>
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<p>1 A. Do I have any of the papers with me?</p> <p>2 Oh, no, I need the papers. So those</p> <p>3 are just the references.</p> <p>4 Maybe, maybe not. I have to look at</p> <p>5 them.</p> <p>6 Q. Okay. And if you find one, will you</p> <p>7 advise --</p> <p>8 A. Sure.</p> <p>9 Q. -- Counsel here so she can advise</p> <p>10 us?</p> <p>11 A. Sure.</p> <p>12 Q. Okay. Number 7. TVT-O is</p> <p>13 associated with an unacceptably high rate of</p> <p>14 chronic pain.</p> <p>15 Tell me about that. What do you</p> <p>16 rely on to support that opinion?</p> <p>17 A. Sure. So, again, you get to the</p> <p>18 fact that you're operating in a space that causes</p> <p>19 the kind of pain that is hard to get rid of --</p> <p>20 Q. Okay.</p> <p>21 A. -- and that's unacceptable.</p> <p>22 Q. Okay. Now, are we talking about a</p> <p>23 particular kind of pain here?</p> <p>24 A. We are talking about groin pain and</p>	<p>1 walked into your office without chronic pain and</p> <p>2 they're to take care -- they're to have their</p> <p>3 urinary incontinence taken care of, they should</p> <p>4 not walk away with chronic debilitating pain.</p> <p>5 Q. Is --</p> <p>6 A. So it's unacceptable.</p> <p>7 Q. Okay. Any level? Anything above</p> <p>8 zero percent?</p> <p>9 A. If my patient walked into my office</p> <p>10 and they had that surgery done, and they came to</p> <p>11 me and they said they are having this pain, I --</p> <p>12 I would take it very seriously.</p> <p>13 And likely I would remove that sling</p> <p>14 very quickly before the scarring sets in and she</p> <p>15 has chronic pain.</p> <p>16 Q. Okay. Number 9.</p> <p>17 By the way, I'll tell you. We</p> <p>18 looked at your reference material. We didn't see</p> <p>19 the paper listed by Denson.</p> <p>20 A. Pardon me?</p> <p>21 Q. We didn't list -- see a paper listed</p> <p>22 by the author you referenced.</p> <p>23 A. Oh, okay. Well, you can -- it's</p> <p>24 probably -- I'll find it for you. That's fine.</p>

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<p>1 Q. Okay. 9 and 10 kind of are related</p> <p>2 to each other. Tell me about those.</p> <p>3 A. So this is the same sort of thing</p> <p>4 that we talked about.</p> <p>5 If a patient walks into my office,</p> <p>6 not having had this pain but purely for treatment</p> <p>7 of urinary incontinence, and then they wake up</p> <p>8 after the procedure, they have pain that</p> <p>9 persists, given what I told you about the course</p> <p>10 of unpredictable -- unpredictable course of the</p> <p>11 slings that has been shown both in the literature</p> <p>12 and can also be -- be seen by ultrasound, it's</p> <p>13 safe to conclude that they're having a</p> <p>14 device-related complication.</p> <p>15 Q. Again, Doctor, I'm going to ask you</p> <p>16 if you're referencing there any specific</p> <p>17 literature upon which you rely to support your</p> <p>18 opinion.</p> <p>19 A. The -- I believe we have the</p> <p>20 references in the list of references, I believe.</p> <p>21 Q. Okay. So everything I would find in</p> <p>22 your list of reliance materials in Exhibit B to</p> <p>23 your report?</p> <p>24 A. Pardon me?</p>	<p>1 record.</p> <p>2 THE VIDEOGRAPHER: Time now is</p> <p>3 12:32. We are going off the record.</p> <p>4 (Recess - 12:32 p.m.</p> <p>5 - 12:32 p.m.)</p> <p>6 THE VIDEOGRAPHER: Time now is</p> <p>7 12:32. We are back on the record.</p> <p>8 (Document marked, for</p> <p>9 identification purposes, as Defendant's</p> <p>10 Exhibit No. 3.)</p> <p>11 BY MR. OTTAWAY:</p> <p>12 Q. Doctor, we are back on the record</p> <p>13 and you've been handed an exhibit here, which is</p> <p>14 a part of your report labeled "Reliance</p> <p>15 Materials."</p> <p>16 Can you go through there and</p> <p>17 reference, if you can, the specific support for</p> <p>18 the opinions we just discussed.</p> <p>19 MS. THOMPSON: Object to form.</p> <p>20 Well, answer that question</p> <p>21 however you want.</p> <p>22 THE WITNESS: So -- so what you a</p> <p>23 handed me is a list of publications, you</p> <p>24 know, that we have coded and it's just a</p>
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<p>1 Q. Everything you rely on is contained</p> <p>2 in Exhibit B to your report, which is your</p> <p>3 reliance materials?</p> <p>4 MS. THOMPSON: Do you have</p> <p>5 Exhibit B that he could --</p> <p>6 MS. FISCHER: Go off the record,</p> <p>7 please.</p> <p>8 MS. THOMPSON: You don't have to</p> <p>9 go off the record to mark an exhibit.</p> <p>10 MS. FISCHER: Are you refusing my</p> <p>11 request to go off the record?</p> <p>12 MS. THOMPSON: Well, we're taking</p> <p>13 a lot of breaks.</p> <p>14 MS. FISCHER: Two. We've taken</p> <p>15 two. Are you refusing my request to go off</p> <p>16 the record?</p> <p>17 MS. THOMPSON: No, I'm not</p> <p>18 refusing. I'm just suggesting if you're</p> <p>19 going to do something that takes 10</p> <p>20 seconds, it's probably more efficient to</p> <p>21 stay on the record.</p> <p>22 MS. FISCHER: Are we off the</p> <p>23 record or not?</p> <p>24 MS. THOMPSON: Yeah. Go off the</p>	<p>1 list of it. So what I require right now is</p> <p>2 the actual articles for me to go through</p> <p>3 and tell you where they are.</p> <p>4 BY MR. OTTAWAY:</p> <p>5 Q. Doctor, they didn't give them to us</p> <p>6 and, I mean, I guess they're available.</p> <p>7 But do you have anything in your</p> <p>8 mind right now, any specific article you're</p> <p>9 referencing?</p> <p>10 MS. THOMPSON: And -- and you</p> <p>11 also have to which opinion you're referring</p> <p>12 to.</p> <p>13 MR. OTTAWAY: The same one we</p> <p>14 were just discussing, counsel. I haven't</p> <p>15 moved on.</p> <p>16 MS. THOMPSON: Okay. Which one</p> <p>17 are we on?</p> <p>18 MR. OTTAWAY: I'm sorry. Let's</p> <p>19 go back. I think it was 8 and 9.</p> <p>20 THE WITNESS: 9 and 10.</p> <p>21 MR. OTTAWAY: 9 and 10. See, I</p> <p>22 was pretty close. The doctor knew all the</p> <p>23 time.</p> <p>24 MS. THOMPSON: Okay. Numbers 9</p>

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<p style="text-align: right;">Page 106</p> <p>1 and 10.</p> <p>2 THE WITNESS: So there are a lot</p> <p>3 of articles supporting this. I have to see</p> <p>4 the actual articles to put it out for you.</p> <p>5 BY MR. OTTAWAY:</p> <p>6 Q. Okay. So you're not able to tell me</p> <p>7 just looking at the --</p> <p>8 A. Yeah. They --</p> <p>9 Q. -- exhibit I handed you?</p> <p>10 A. They are a lot of articles and there</p> <p>11 are a lot of them that each of them looks at a</p> <p>12 different point, and I'll be happy to give you</p> <p>13 that information if I have the actual papers.</p> <p>14 Q. Okay. Just keep going there,</p> <p>15 Doctor, and I want to take all the other opinions</p> <p>16 and ask you the same kind of thing.</p> <p>17 Do you have any particular support</p> <p>18 you're relying on for them, or is this just,</p> <p>19 again, contained somewhere in your reliance</p> <p>20 materials?</p> <p>21 A. For the what question?</p> <p>22 Q. The rest of them, 10 on.</p> <p>23 A. Yeah, I think they're all in the</p> <p>24 references that we have given you.</p>	<p style="text-align: right;">Page 108</p> <p>1 all of them do that?</p> <p>2 BY MR. OTTAWAY:</p> <p>3 Q. Yes.</p> <p>4 A. No. I mean, we have seen slings</p> <p>5 that don't do that.</p> <p>6 Q. Okay. Tell me who manufactured</p> <p>7 those slings.</p> <p>8 A. Who manufactures the slings that</p> <p>9 don't roll?</p> <p>10 Q. Yes.</p> <p>11 A. Well, for example, the -- most of</p> <p>12 the TVT type slings that we look at, they don't</p> <p>13 roll. They sit straight.</p> <p>14 Q. Well, no. My question was</p> <p>15 specifically limited to transobturator slings.</p> <p>16 A. Well, the TVT-Os we have looked at,</p> <p>17 they roll and they cause problems. And I told</p> <p>18 you we don't use TOTs anymore.</p> <p>19 Q. Okay. Well, have you done a study,</p> <p>20 though, of TOTs in the same way that you have</p> <p>21 looked at TVT-Os to determine whether they roll,</p> <p>22 fray, curl?</p> <p>23 A. Uh-huh.</p> <p>24 Q. Tell me what you found.</p>
<p style="text-align: right;">Page 107</p> <p>1 Q. Okay. You have an opinion, Doctor,</p> <p>2 that the TVT-O is defective in design.</p> <p>3 Exactly what defects in design do</p> <p>4 you reference?</p> <p>5 A. Well, one thing we had talked about</p> <p>6 earlier is just the weave of the mesh, where the</p> <p>7 opening surgeon in the removal of the sheet, the</p> <p>8 sling frays and so cords and so that would change</p> <p>9 the properties of the mesh.</p> <p>10 Q. Okay. Is that a -- is that a</p> <p>11 function of it being made out of polypropylene?</p> <p>12 A. It's a function of design.</p> <p>13 Q. Okay. Tell me the design function</p> <p>14 that it results from. Tell me what specifically</p> <p>15 about the design you're critical of.</p> <p>16 A. Well, the fact that it's coils.</p> <p>17 It's ropes. It doesn't stay flat. The way the</p> <p>18 fact that it has edges that fray, you know.</p> <p>19 Those are the design flaws.</p> <p>20 Q. Okay. Does the -- is this a common</p> <p>21 characteristic of all transobturator slings, both</p> <p>22 inside-out and outside-in?</p> <p>23 MS. THOMPSON: Object to form.</p> <p>24 THE WITNESS: So you're asking if</p>	<p style="text-align: right;">Page 109</p> <p>1 A. Well, the -- I think that both TOTs</p> <p>2 and TVT-Os can behave the same to some degree.</p> <p>3 The -- the ones that I have looked at have been</p> <p>4 the TVT-O and the Bard product, and I know those</p> <p>5 ones roll and cause issues.</p> <p>6 Q. Okay. Any others that you've looked</p> <p>7 at?</p> <p>8 A. There are some others, but off the</p> <p>9 top of my head, I would say that we have looked</p> <p>10 at some Boston Scientific products that also do</p> <p>11 the same thing. Their transobturator. So those</p> <p>12 are the three I can think of.</p> <p>13 Q. So TVT-O is not unique in that</p> <p>14 regard?</p> <p>15 MS. THOMPSON: Object to form.</p> <p>16 THE WITNESS: The TVT-O probably</p> <p>17 is not unique in that regard, and but we</p> <p>18 are not using TOTs or TVT-Os.</p> <p>19 BY MR. OTTAWAY:</p> <p>20 Q. Doctor, if you can go to page 26 of</p> <p>21 your report. Middle paragraph starts "There</p> <p>22 are." Are you with me?</p> <p>23 A. Sure.</p> <p>24 Q. Okay. Tell me what in your opinion</p>

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<p>1 would have provided a safer alternative.</p> <p>2 A. Well, in our practice, we are</p> <p>3 basically using the retropubic devices. We're</p> <p>4 using the TVT type devices.</p> <p>5 Q. TVT devices manufactured by Ethicon?</p> <p>6 A. Ethicon, Boston Scientific. You</p> <p>7 know, depends on what the hospital is providing</p> <p>8 us.</p> <p>9 Q. So when you say "safer alternative,"</p> <p>10 you mean retropubic TVT devices?</p> <p>11 A. Yeah, that's the --</p> <p>12 MS. THOMPSON: Object to form.</p> <p>13 THE WITNESS: Those are the safer</p> <p>14 things.</p> <p>15 MR. OTTAWAY: You have to let her</p> <p>16 get her objection out, Doctor.</p> <p>17 Do you have an objection,</p> <p>18 counsel?</p> <p>19 MS. THOMPSON: Object. Yeah, I</p> <p>20 object to form.</p> <p>21 MR. OTTAWAY: Thank you.</p> <p>22 BY MR. OTTAWAY:</p> <p>23 Q. You may answer, Doctor. I'm sorry.</p> <p>24 If you can remember the question?</p>	<p>1 MS. THOMPSON: Object to form.</p> <p>2 BY MR. OTTAWAY:</p> <p>3 Q. -- when it comes to safety and</p> <p>4 efficacy?</p> <p>5 A. I'm aware of literature that say</p> <p>6 they are not equivalent.</p> <p>7 Q. That wasn't my question again,</p> <p>8 Doctor.</p> <p>9 If you can answer my question. I</p> <p>10 appreciate your answer, but can you answer my</p> <p>11 question?</p> <p>12 A. Yes, there is literature saying that</p> <p>13 depending on the end point that they were looking</p> <p>14 at, those end points are equivalent.</p> <p>15 Q. Okay. Thank you.</p> <p>16 I noticed here at the last page of</p> <p>17 your report that you've already told us that</p> <p>18 you've stopped using TVT-O; correct?</p> <p>19 A. Uh-huh. True.</p> <p>20 Q. Are you aware of any academic center</p> <p>21 currently using TVT-O?</p> <p>22 A. No, but that doesn't mean somebody</p> <p>23 out there is not using it.</p> <p>24 Q. Have you made any effort to search</p>
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<p>1 A. Yeah. So we have -- we have moved</p> <p>2 to the more retropubic slings.</p> <p>3 Q. Okay.</p> <p>4 A. And we don't have TVT-Os on the</p> <p>5 shelf.</p> <p>6 Q. Okay. And those include TVT devices</p> <p>7 made by Ethicon?</p> <p>8 A. TVT devices by -- made by Ethicon.</p> <p>9 Q. Okay. And when you say "safer</p> <p>10 alternative," that's what you mean?</p> <p>11 MS. THOMPSON: Object to form.</p> <p>12 THE WITNESS: That's what we are</p> <p>13 using now.</p> <p>14 BY MR. OTTAWAY:</p> <p>15 Q. Okay. Well, no. I'm asking you if</p> <p>16 that is the safer alternative you're referencing</p> <p>17 at page 26 of your report?</p> <p>18 A. Yes. We are avoiding transobturator</p> <p>19 space and going to retropubic in appropriate</p> <p>20 patients.</p> <p>21 Q. Okay. Is there medical literature,</p> <p>22 Doctor, of what you're aware in peer-reviewed</p> <p>23 journals which suggests that TVT devices and</p> <p>24 TVT-O devices are equivalent --</p>	<p>1 and find out that information?</p> <p>2 A. The people I have talked to and the</p> <p>3 people who are within my communication space are</p> <p>4 not using it, but it doesn't mean somebody out</p> <p>5 there is not.</p> <p>6 Q. Okay. Even in an academic center?</p> <p>7 A. True.</p> <p>8 MR. OTTAWAY: How are we doing on</p> <p>9 time, Mr. Videographer?</p> <p>10 THE VIDEOGRAPHER: Nine minutes</p> <p>11 to go.</p> <p>12 MR. OTTAWAY: All right. Good.</p> <p>13 We'll finish out the nine minutes then.</p> <p>14 BY MR. OTTAWAY:</p> <p>15 Q. You have reviewed the IFU for TVT-O,</p> <p>16 Doctor?</p> <p>17 A. Yes, I did.</p> <p>18 Q. When you were performing TVT-O</p> <p>19 surgeries, had you reviewed it prior to doing</p> <p>20 them?</p> <p>21 A. Yes.</p> <p>22 Q. Did you also conduct your own review</p> <p>23 of literature to determine how other people were</p> <p>24 doing with the TVT-O or TOT device?</p>

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<p>1 A. I believe when we started using</p> <p>2 either of them, you know, we reviewed the</p> <p>3 available literature and we read the IFU.</p> <p>4 Q. And that's why you say you practice</p> <p>5 evidence-based medicine; correct? Because that's</p> <p>6 something you do, review the literature before</p> <p>7 you start using a product?</p> <p>8 MS. THOMPSON: Object to form.</p> <p>9 THE WITNESS: We review the</p> <p>10 literature and read the IFU before we use</p> <p>11 the product.</p> <p>12 BY MR. OTTAWAY:</p> <p>13 Q. But you don't do one to the</p> <p>14 exclusion of the other; correct?</p> <p>15 A. True.</p> <p>16 Q. And you would expect other doctors</p> <p>17 sharing your specialty to do the same. True?</p> <p>18 MS. THOMPSON: Object to form.</p> <p>19 THE WITNESS: True.</p> <p>20 BY MR. OTTAWAY:</p> <p>21 Q. Now, you talk about adverse</p> <p>22 reactions that are listed in the IFU.</p> <p>23 A. What page?</p> <p>24 Q. I'm not trying to fool you here,</p>	<p>1 A. Well, the IFU says transitory local</p> <p>2 irritation and transitory foreign body response,</p> <p>3 which is what you expect the body to do when it's</p> <p>4 healing. So I really think that Ethicon</p> <p>5 minimized the extent of the problems that was</p> <p>6 occurring in the body.</p> <p>7 Q. And were those problems noted in the</p> <p>8 literature to which you've referred?</p> <p>9 A. So the question is?</p> <p>10 Q. Well, you've talked about the IFU,</p> <p>11 and I know you disagree with the way it's worded.</p> <p>12 A. Uh-huh.</p> <p>13 Q. But regardless of how it's worded,</p> <p>14 was that information available in the</p> <p>15 peer-reviewed literature that you've referenced?</p> <p>16 You've said you've looked at</p> <p>17 peer-reviewed literature and the IFU.</p> <p>18 MS. THOMPSON: Object to form of</p> <p>19 the question.</p> <p>20 THE WITNESS: In terms of TVT-O?</p> <p>21 BY MR. OTTAWAY:</p> <p>22 Q. Yes.</p> <p>23 MS. THOMPSON: I'm sorry. And</p> <p>24 misstates his previous testimony.</p>
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<p>1 Doctor. It's page 24 of your report if you want</p> <p>2 to go to it.</p> <p>3 A. Okay.</p> <p>4 Q. What adverse reactions are listed in</p> <p>5 the IFU?</p> <p>6 A. So you want me to pull out the IFU?</p> <p>7 Q. You're free to refer to it, Doctor.</p> <p>8 If you can't tell me without referring to it, of</p> <p>9 course you can.</p> <p>10 A. Okay. (Reviewing document).</p> <p>11 So we have the warning and</p> <p>12 precautions and the adverse reactions section.</p> <p>13 What's your question about it?</p> <p>14 Q. For example, is nerve pain</p> <p>15 mentioned?</p> <p>16 A. Yes.</p> <p>17 Q. We discussed scarring previously.</p> <p>18 As a physician, did you know</p> <p>19 scarring was a potential?</p> <p>20 A. Yes.</p> <p>21 Q. Did you know inflammatory or foreign</p> <p>22 body reaction was a potential?</p> <p>23 A. With the TVT-O insertion?</p> <p>24 Q. Yes.</p>	<p>1 BY MR. OTTAWAY:</p> <p>2 Q. She has to get it all out, Doctor,</p> <p>3 and she's entitled to.</p> <p>4 A. Yeah, in terms of the TVT-O being a</p> <p>5 new device, we went with the literature and IFU.</p> <p>6 Q. Okay. Now, you talk about some of</p> <p>7 the adverse reactions on page 25 of your report?</p> <p>8 A. Sure.</p> <p>9 Q. Chronic pain. Is there a difference</p> <p>10 between chronic pain and chronic pain syndromes?</p> <p>11 A. Yes.</p> <p>12 Q. Okay. Tell me the difference.</p> <p>13 A. Chronic pain is -- can be localized.</p> <p>14 Chronic pain syndrome can be a constellation of</p> <p>15 different systems.</p> <p>16 Q. And which are you referring to here</p> <p>17 when you say "adverse reactions"?</p> <p>18 A. Could be both.</p> <p>19 Q. Okay. So it could be both.</p> <p>20 And are both noted and contained in</p> <p>21 the peer-reviewed literature? Supported by the</p> <p>22 peer-reviewed literature?</p> <p>23 A. In terms of?</p> <p>24 Q. TVT-O.</p>

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<p>1 But at the same time, depending on</p> <p>2 how, whether it's a TVT or a mesh that is device</p> <p>3 inserted, you know, if there is any obstruction</p> <p>4 to the -- to the bladder also, you can get UTI.</p> <p>5 So they can melt into each other.</p> <p>6 Q. Okay. What I'm hearing you saying</p> <p>7 is infection -- bladder infections can be present</p> <p>8 with all forms of mesh in addition to TVT-O.</p> <p>9 Is that a correct statement? Is my</p> <p>10 statement correct?</p> <p>11 A. Well, theoretically, you should not</p> <p>12 have it as much with mesh --</p> <p>13 Q. Okay.</p> <p>14 A. -- itself but more with the TVT-O.</p> <p>15 Q. Okay. So that's a question of</p> <p>16 frequency, I guess?</p> <p>17 A. Uh-huh. True.</p> <p>18 Q. Both can do it, but in your</p> <p>19 judgment, TVT-O or TOT devices do it more often?</p> <p>20 A. Repeat that question. Sorry about</p> <p>21 that. Do you want to?</p> <p>22 Q. Well, yeah, it's all right.</p> <p>23 A. Just make sure.</p> <p>24 Q. I want to make sure we communicate</p>	<p>1 with the TVT-Os, if they're roping and rolling</p> <p>2 and they're a tube type and they're causing</p> <p>3 outflow problems to the bladder, they can also</p> <p>4 contribute to the bladder infection.</p> <p>5 Q. Okay. And this roping and rolling</p> <p>6 you're discussing, is that, in your opinion,</p> <p>7 unique to TVT-O or TOT devices?</p> <p>8 A. They are more often seen in those</p> <p>9 conditions.</p> <p>10 Q. Okay. So not unique but more</p> <p>11 frequent. Fair?</p> <p>12 A. The -- so we are talking about the</p> <p>13 roping and curling of the tissue?</p> <p>14 Q. Yes.</p> <p>15 A. Yeah. I mean, just because of the</p> <p>16 anatomy going from side to side, you see that.</p> <p>17 Q. More frequently? I mean, it's a</p> <p>18 question of frequency? Not that it doesn't rope</p> <p>19 or roll in other meshes, it's just more frequent</p> <p>20 in?</p> <p>21 A. Well, that's the condition that we</p> <p>22 have seen it in.</p> <p>23 Q. Okay.</p> <p>24 A. So...</p>
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<p>1 so that you know that when you've answered my</p> <p>2 question, you've answered it with your opinion.</p> <p>3 Fair enough?</p> <p>4 A. Well, I just want to make sure you</p> <p>5 understand what I said.</p> <p>6 Q. Yes. Yeah. What I'm understanding</p> <p>7 you to say is: Infection can result from any</p> <p>8 mesh. Vaginal infection can result from any</p> <p>9 mesh.</p> <p>10 A. Uh-huh.</p> <p>11 Q. But in your opinion, urinary tract</p> <p>12 infections or bladder infections would be more</p> <p>13 common with TVT-O than with TVT mesh?</p> <p>14 A. Yeah. The thing is that their</p> <p>15 mechanisms can be different, too.</p> <p>16 Q. Okay. And that's --</p> <p>17 A. That's what I was trying to stress.</p> <p>18 Q. Yeah. Tell me about how their</p> <p>19 mechanisms can be different.</p> <p>20 A. Well, what I was saying is that with</p> <p>21 the vaginal meshes that are placed, you know, if</p> <p>22 they're coming through and they're causing</p> <p>23 vaginal discharge, that would be the contributing</p> <p>24 factor. And that's true for TVT-O as well, but</p>	<p>1 Q. I'm still not sure I got the answer</p> <p>2 there.</p> <p>3 Do you see roping and rolling in</p> <p>4 other forms of mesh other than TVT-O and TOT?</p> <p>5 A. That's where we have seen it. You</p> <p>6 know, I mean, if somebody puts a TVT and they are</p> <p>7 placed in a very tight manner, you know, I guess</p> <p>8 they could do that, but we don't see that as</p> <p>9 frequently versus with the TOT and TVT-O we do</p> <p>10 see that.</p> <p>11 Q. So it is a question of frequency.</p> <p>12 That's what I'm trying to get at.</p> <p>13 A. Yeah.</p> <p>14 Q. Okay. De novo urinary symptoms. Is</p> <p>15 that something unique to TVT-O or TOT devices or</p> <p>16 something that is present in as a potential in</p> <p>17 vaginal surgery or mesh surgeries in general?</p> <p>18 A. De novo urinary symptoms could be</p> <p>19 associated with both TVT-O and TVT type slings.</p> <p>20 Q. Okay. Hypspareunia. What do you</p> <p>21 mean by hypspareunia, in quotes?</p> <p>22 A. Again, because of the anatomy and</p> <p>23 the way that the sling would travel causing that</p> <p>24 bridge or scarring. As male tries to enter and</p>

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<p>1 have intercourse, they have pain.</p> <p>2 Q. And is that something unique to</p> <p>3 TVT-O or TOT devices or can that be present with</p> <p>4 any TVT or mesh device?</p> <p>5 A. The location would be different,</p> <p>6 depending on where you have the problem.</p> <p>7 Q. Okay. Other than location?</p> <p>8 A. So the presentation would be</p> <p>9 different for TVT-O device versus something that</p> <p>10 is placed deeper.</p> <p>11 Q. Okay. Explain that to me, if you</p> <p>12 will. I want to understand.</p> <p>13 A. So if you have a mesh under the</p> <p>14 bladder or over the rectum and it's working</p> <p>15 through, so the male can enter, but they would go</p> <p>16 halfway in, and they feel the mesh then and that</p> <p>17 would hurt them versus with the TVT-O is very</p> <p>18 much, you know, closer to the outside. So they</p> <p>19 would feel it. They cannot get very far.</p> <p>20 Q. Okay. So it would be a question of</p> <p>21 location within the vagina then?</p> <p>22 A. Yes.</p> <p>23 Q. Thank you. I think I understand.</p> <p>24 Is there any difference in the</p>	<p>1 I asked you: Do you hold yourself</p> <p>2 out as an expert in biomaterials?</p> <p>3 A. I'm not a biomaterial engineer.</p> <p>4 Q. All right. Doctor, I'd like to ask</p> <p>5 you a question. If you want to refer to page 27,</p> <p>6 but it's referred to in several pages in your</p> <p>7 report.</p> <p>8 What is your definition of a</p> <p>9 "community doctor"?</p> <p>10 A. A community doctor? Where do I --</p> <p>11 ah, I see here.</p> <p>12 Community doctors are physicians who</p> <p>13 are working in the community. Probably</p> <p>14 physicians in nonacademic centers.</p> <p>15 Q. And would they be gynecologists,</p> <p>16 urogynecologists?</p> <p>17 A. Or -- or physicians in a non- --</p> <p>18 non-tertiary type health centers.</p> <p>19 Q. Would they be doctors who had access</p> <p>20 to the same reference material that you refer to</p> <p>21 in your Exhibit B to your report?</p> <p>22 A. They would have access to it, but</p> <p>23 remember, for me I'm always reading articles</p> <p>24 continuously where those physicians may have</p>
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<p>1 chemical composition of the polypropylene used in</p> <p>2 TVT-O and TVT mesh made by Ethicon that you're</p> <p>3 aware of?</p> <p>4 MS. THOMPSON: Object to form.</p> <p>5 The TVT-O compared to TVT or TVT-O and TVT</p> <p>6 compared to other mesh?</p> <p>7 MR. OTTAWAY: I actually asked</p> <p>8 the question TVT-O and TVT manufactured by</p> <p>9 Ethicon, I believe.</p> <p>10 THE WITNESS: So comparing TVT-O</p> <p>11 to --</p> <p>12 MS. THOMPSON: Object to the form</p> <p>13 of the question.</p> <p>14 THE WITNESS: -- TVT? They're</p> <p>15 both polypropylene.</p> <p>16 BY MR. OTTAWAY:</p> <p>17 Q. Okay. Are you aware of any</p> <p>18 differences in the chemical makeup of the two?</p> <p>19 A. I think they are both polypropylene.</p> <p>20 Q. Okay. And do you hold yourself out</p> <p>21 as an expert in biomaterials?</p> <p>22 A. I know as much as it pertains to my</p> <p>23 work.</p> <p>24 Q. Again, that wasn't my question.</p>	<p>1 certain societies they belong to or they would --</p> <p>2 they may read one or the other journal.</p> <p>3 Q. They can be doctors who are</p> <p>4 specializing in your specialty? Members of the</p> <p>5 same societies you're members of?</p> <p>6 A. So are there community physicians</p> <p>7 who are urogynecologists? There are community</p> <p>8 urogynecologists as well.</p> <p>9 Q. Now, the reason I ask that is</p> <p>10 because if you'll go to page 22?</p> <p>11 A. Uh-huh.</p> <p>12 Q. The second sentence on that page.</p> <p>13 That phrase "doctors in the community." Not</p> <p>14 community doctors, but "Doctors in the</p> <p>15 community --</p> <p>16 A. Uh-huh.</p> <p>17 Q. -- are often unaware of the risks of</p> <p>18 mesh."</p> <p>19 You see that sentence?</p> <p>20 A. I see that.</p> <p>21 Q. Are you aware of any study that</p> <p>22 supports that opinion? It's not referenced to</p> <p>23 anything.</p> <p>24 A. Well, I think we draw that from our</p>

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<p>1 studies where we were in Oklahoma at a tertiary 2 care center, and we did a study where we saw 75 3 percent of patients who came to us with mesh 4 complications with the sling complications. 5 They -- when we asked them who 6 referred you to us, they said, you know, we -- I 7 came here based on the referral from a friend or 8 the church. And when we talked to the 9 physicians, they were like OB-GYNs, know this was 10 a problem. So it's actually documented in the 11 literature how -- how these mesh complications 12 may be seen, but most often they are told that 13 maybe just give the patient estrogen and it would 14 go away and it would end. 15 Q. Is estrogen an accepted form of 16 therapy for some mesh complications? 17 A. You know, to the -- this type of 18 mesh complications pertaining to TVT-O and such 19 was something that I think crept up on the 20 community, and a lot of times neither the 21 community physicians nor us knew how to deal with 22 them. 23 I mean, they came about and we were 24 looking at ways to take care of the mesh problem,</p>	<p>1 the community? 2 A. It was pretty much a media blast. 3 So whoever followed that probably learned about 4 it quickly. 5 Q. And so your statement, 6 "Unfortunately, doctors in the community are 7 often not aware of the risks of mesh" would 8 predate 2008? 9 MS. THOMPSON: Object to form. 10 THE WITNESS: Well, the study 11 that we did was after that time. So 12 doesn't seem like that filtrated into the 13 community. 14 BY MR. OTTAWAY: 15 Q. And did you try to in your study -- 16 and please refer me to the study you're 17 referencing if it's in your materials there. 18 A. Sure. 19 Q. I'd like to know which study it is. 20 A. Uh-huh. It's the -- in the Oklahoma 21 Medical Journal. I don't know what year it was, 22 whether it's 2012 or '13. So... 23 Q. Okay. Did you make an effort in 24 that study to determine whether this statement</p>
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<p>1 take care of the sling erosion problem 2 nonsurgically. We did try estrogen and you may 3 find references in the literature that it was 4 advocated at one point, but it really fell out of 5 favor because it just didn't work. 6 Q. Okay. There was an FDA paper you 7 reference in your report issued in 2008. 8 A. Okay. 9 Q. Are you aware of that? 10 A. Yes. 11 Q. Did that FDA paper warn of the risks 12 associated with mesh implantation? 13 A. Okay. 14 Q. Did it? 15 A. So what's the question? 16 Q. My question is: Did the FDA 2008 17 paper address the issue of -- 18 A. Yeah, that was the FDA warning, 19 warning of. 20 Q. -- risks of mesh? 21 A. They were -- they were alerting the 22 community of -- of complications associated with 23 the mesh and the sling that they were seeing. 24 Q. Okay. And did that go to doctors in</p>	<p>1 "Doctors in the community are not aware of the 2 risks of mesh" was post or pre-2008, the 3 implantation? 4 A. The study was done in 2012, '13, 5 whenever it was published. So, I mean, you can 6 draw a conclusion. If the warning came in 2008 7 and the study is published a few years later 8 whether the physicians really got the message or 9 not. I think that the -- you know, they -- they 10 didn't refer us the patients and it doesn't seem 11 like they were aware of the mesh problems that 12 was going on. Whether -- yeah, go ahead. 13 Q. No, go ahead. Finish your answer, 14 please. 15 A. So the study basically said about 75 16 percent of people were self-referred but not 17 referred by the surgeon who did their surgery. 18 Q. And it's from that study you 19 determined that "Doctors in the community are 20 often not aware of the risks of mesh"? 21 A. That's -- that's the -- that's what 22 we have observed. 23 Q. And did that study -- and again, you 24 know, I know the study you're referencing on that</p>

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<p>1 one.</p> <p>2 A. Uh-huh.</p> <p>3 Q. Did that make any effort to</p> <p>4 determine whether the mesh was implanted pre or</p> <p>5 post the FDA 2008 advisory?</p> <p>6 A. I see what you're asking.</p> <p>7 So these are the patients who -- I</p> <p>8 mean, they could have had their mesh implanted</p> <p>9 before that as well. We didn't look at the exact</p> <p>10 date of implantation.</p> <p>11 Q. Okay. Now, the last point I want to</p> <p>12 discuss with you -- because we're running out of</p> <p>13 time, and I want to take one very brief break for</p> <p>14 about 10 minutes left to make sure I got</p> <p>15 everything but -- is your opinion that TVT-O or</p> <p>16 TOT devices are more difficult to remove than</p> <p>17 other forms of TVT mesh.</p> <p>18 Tell me about your opinion in that</p> <p>19 regard.</p> <p>20 A. So it, again, goes to the matter of</p> <p>21 the space utilized to put those slings in. So if</p> <p>22 we had a TVT mesh, if you want to remove the</p> <p>23 whole thing, you could go retropubically,</p> <p>24 transvaginally and you could be pretty sure that</p>	<p>1 if it's pain issue, groin pain issue, leg pain</p> <p>2 that is radiating from the obturator territory.</p> <p>3 You know, the -- if that was really the thing</p> <p>4 that I was worried about, then, you know, I would</p> <p>5 probably sit with the patient and tell them if</p> <p>6 that's the issue, then I would have to make that</p> <p>7 groin incision and approach it that way to make</p> <p>8 sure we get everything. But it's -- it's one of</p> <p>9 those things that adds time to the surgery.</p> <p>10 Q. So in your case, you can get it. It</p> <p>11 just adds a little more time to the surgery?</p> <p>12 A. Not a little time --</p> <p>13 MS. THOMPSON: Object to the</p> <p>14 form.</p> <p>15 BY MR. OTTAWAY:</p> <p>16 Q. That's fine. She got her right to</p> <p>17 object.</p> <p>18 A. No. It probably takes about an hour</p> <p>19 on each side.</p> <p>20 Q. Okay. It adds an hour more?</p> <p>21 A. On each side.</p> <p>22 Q. Per side?</p> <p>23 A. Yeah.</p> <p>24 Q. Anything else?</p>
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<p>1 you could remove 100 percent of it.</p> <p>2 With the transobturator tape or the</p> <p>3 TVT-O, as we discussed, your arm of the sling</p> <p>4 goes lateral and behind the bone and disappears.</p> <p>5 So most skilled surgeons -- again,</p> <p>6 has been a learning cycle for a lot of people who</p> <p>7 were not used to this area -- that's as far as</p> <p>8 they can go. So there is inevitably some mesh</p> <p>9 left in a patient where they can come back and</p> <p>10 say, I still have a problem there.</p> <p>11 Q. Okay. How about in your experience,</p> <p>12 are you able to access and remove that mesh?</p> <p>13 A. I -- I try to remove as much as I</p> <p>14 can, but I -- because you get into such a</p> <p>15 difficult space, most often that's where we will</p> <p>16 stop. You know, because then the idea of having</p> <p>17 to go through the groin to approach that space</p> <p>18 is -- it's very challenging as well.</p> <p>19 Q. Now, having removed the mesh other</p> <p>20 than the mesh you've just described, what</p> <p>21 consequences would result from leaving just that</p> <p>22 portion of the mesh in?</p> <p>23 A. Well, the patient is coming to you</p> <p>24 for pain, mesh complications problems, especially</p>	<p>1 A. To remove that mesh?</p> <p>2 Q. Yes.</p> <p>3 A. Well, you may be left with the</p> <p>4 consequences that despite you doing all that</p> <p>5 surgery, the nerve is still scarred and the pain</p> <p>6 wouldn't go away.</p> <p>7 Q. Have you done a study, Doctor, to</p> <p>8 determine the percentage of patients or can you</p> <p>9 refer to one in the literature that you rely upon</p> <p>10 today --</p> <p>11 A. Uh-huh.</p> <p>12 Q. -- that discusses the percentage of</p> <p>13 patients who will have that residual mesh or</p> <p>14 suffer a consequence from it?</p> <p>15 MS. THOMPSON: Object to form.</p> <p>16 THE WITNESS: Pardon me?</p> <p>17 MS. THOMPSON: Object to form of</p> <p>18 that question.</p> <p>19 THE WITNESS: Yeah.</p> <p>20 MS. THOMPSON: It's compound.</p> <p>21 THE WITNESS: Yeah, there are</p> <p>22 studies -- again if you want me to name it,</p> <p>23 I have to look at the whole article and</p> <p>24 find it for you. But there are studies</p>

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